Remarks

Reconsideration and allowance of this application, as amended, are respectfully requested.

Claims 1, 2, 4, 5, 9, 10, and 17 have been amended. New claim 21 has been added. Claims 1-21 are now pending in the application. Claims 1, 2, and 17 are independent. The rejections are respectfully submitted to be obviated in view of the amendments and remarks presented herein. No new matter has been introduced through the foregoing amendments.

Each of claims 1, 2, 9, and 17 has been amended in response to the examiner's comments at Office Action page 8 regarding the features of the invention that were previously presented. Each of claims 1, 2, 9, and 17 now defines an embodiment of the invention in which the blood treatment element is "configured for hemodiafiltration."

Claim 21 has been added to further define the scope of protection sought for Applicants' invention. Claim 21 defines the apparatus that is associated with the postdilution method embodiment of the invention.

Entry of each of the amendments is respectfully requested.

35 U.S.C. § 103(a) - Twardowski and Polaschegg

Claims 1, 2, 4, 5, 8, 9, 12, 14, 15, 17, and 20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S.

Patent No. 6,132,616 to Twardowski et al. (hereinafter "Twardowski") in view of DE 42 40 681 to Polaschegg. The Office Action acknowledges that "Twardowski fails to disclose the presence and use of a substituate pump to move the substituate fluid through the circuit" and relies upon Polaschegg for the disclosure of "a dialysis apparatus with a substitute fluid in chamber 88 connected via line 102 and pump 84 to blood inlet path 36" (Office Action pages 2-3).

The rejection of claims 1, 2, 4, 5, 8, 9, 12, 14, 15, 17, and 20 under § 103(a) based on Twardowski and Polaschegg is respectfully deemed to be obviated. For at least the reasons presented in Applicants' reply filed November 13, 2007, and the following reasons, the combined disclosures of Twardowski and Polaschegg would not have rendered obvious Applicants' presently claimed invention.

By way of review, Applicants' invention addresses the need that "at the end of a dialysis session that the blood present in the extracorporeal circuit [be] returned to the patient as completely as possible" (page 2, paragraph 1). An object of the invention is to provide a method "for a return of blood which is as quantitative as possible . . . [and] which is designed to be even further simplified and more expedient where possible" (page 2, paragraph 2).

Accordingly, Applicants' instant claim 1 defines "a method for the return of blood from a blood treatment apparatus

that includes a blood treatment element *configured for hemodiafiltration*, a first line and a second line each having an outlet, a blood pump, a first valve arranged in the first line, a second valve arranged in the second line, and a predilution port configured to feed a substituate fluid, with a substituate supply line connected to the predilution port and to a substitutate pump."

The predilution method embodiment of the invention includes, *inter alia*, the steps of "operating the substituate pump to displace the blood with transported substituate fluid in a volume-controlled manner until the displaced blood has reached the first line outlet" and "operating the substituate pump to displace the blood through the second line and the blood treatment element with transported substituate fluid in a volume-controlled manner until the displaced blood has reached the second line outlet."

The combined disclosures of Twardowski and Polaschegg do not teach all of Applicants' instant claim features. As acknowledged by the examiner, "Twardowski fails to disclose the presence and use of a substituate pump to move the substituate fluid through the circuit." Twardowski discloses a hemodialyzer. Twardowski's saline bag 164 serves for the filling of the blood tubing system at the start of treatment and for the return of blood at the end of treatment. Applicants note that it is known in hemodialysis to connect a saline solution bag to the arterial line for this purpose and to fill and to purge the blood tubing system by operating the blood tubing pump at the start of treatment. It

is also known to remove the arterial needle from the patient at the end of treatment and to again connect the arterial line to a saline solution bag and to return the blood in the blood tubing system to the patient via the remaining venous connection by operating the pump. According to Twardowski, the bag 164 is connected to the arterial line via a T connector (saline valve 168). The T connector is located upstream of the blood pump 148. For the return of blood at the end of treatment, the "short" path to the patient is first cleared of blood by gravity, then the patient closes a clamp 145a to interrupt this tube section (the other section is closed by the stationary blood pump) (column 14, lines 39-60). The blood pump is then put into operation and the other part of the blood tubing system is purged.

That is not Applicants' claimed method. As indicated above, according to Applicants' predilution embodiment of the invention the method includes the steps of "operating the substituate pump to displace the blood with transported substituate fluid in a volume-controlled manner until the displaced blood has reached the first line outlet" and "operating the substituate pump to displace the blood through the second line and the blood treatment element with transported substituate fluid in a volume-controlled manner until the displaced blood has reached the second line outlet."

And, Twardowski's method is not even suitable for Applicants' claimed "method for the return of blood from a blood

treatment apparatus that includes a blood treatment element configured for hemodiafiltration." The bag should not be connected via the valve 168 during treatment. A corresponding ultrafiltration apparatus would also have to be present to compensate for the substituate flow. Additionally, the patient must manually intervene at times. And, the sequence of the purging steps is different. According to Twardowski, the blood pump is not in motion during the return infusion through the arterial connection and it is in forward operation during the return infusion through the venous connection. But, according to Applicants' claimed invention, the blood pump is in pressure control operation (or, allows throughflow) in the arterial case, while it is stationary in the venous case.

Furthermore, the disclosure of Polaschegg does not rectify the above-described deficiencies of Twardowski. While Polaschegg may disclose an occludable actuator (48, 50), Polaschegg fails to teach Applicants' claimed predilution method for the return of blood from a blood treatment apparatus. In addition, according to Polaschegg, the purge line 44 with the pump 50 serves only to purge the system, but not to provide substitution liquid for the hemodiafiltration treatment. As evident from Polaschegg's Figure 2, lines 98 and 102 are provided for the post-dilution and the pre-dilution - *in addition to* the purge line 50. It is also notable that the pre-dilution line opens into the blood supply line

downstream of the blood pump, since otherwise the speed of the blood pump would have to be adapted for the substituate flow.

Finally, Applicants respectfully disagree with the examiner's assertion at Office Action page 9 that "[t]he method suggested by the prior art and the method claimed by applicant ***appear*** *to perform the same function*, regardless of the order of the steps used in the method" (emphasis added). For all of the reasons identified above, it is clear that the combined disclosures of Twardowski and Polaschegg most certainly would *not* perform Applicants' claimed function.

Thus, the combined disclosures of Twardowski and Polaschegg do not teach all of Applicants' instant claim features. Furthermore, there is simply no teaching in either Twardowski or Polaschegg that would have led one to select the references and combine them in a way that would produce the invention defined by Applicants' presently pending claim 1.

Therefore, the combined disclosures of Twardowski and Polaschegg would not have rendered obvious the invention defined by Applicants' presently pending claim 1. Claims 4, 5, 8, 9, 12, and 14 are allowable because they depend from claim 1, and for other reasons.

Claim 2, which defines the postdilution method embodiment of the invention, is similarly allowable. Claim 15 is allowable because it depends from claim 2, and for other reasons.

35 U.S.C. § 103(a)

Since Twardowski and Polaschegg are applied together in each of the other rejections under § 103(a) -- claim 13 as being unpatentable over Twardowski in view of Polaschegg and further in view of U.S. Patent No. 5,470,483 to Bene et al. ("Bene"); claim 3 as being unpatentable over Twardowski in view of Polaschegg and further in view of U.S. Patent No. 4,770,769 to Schael; claims 6, 7, 10, and 16 as being unpatentable over Twardowski in view of Polaschegg and further in view of U.S. Patent No. 5,783,072 to Kenley et al. ("Kenley"); claim 11 as being unpatentable over Twardowski in view of Polaschegg and further in view of U.S. Patent No. 3,898,017 to Mandroian; claim 18 as being unpatentable over Twardowski in view of Polaschegg and further in view of Schael; and claim 19 as being unpatentable over Twardowski in view of Polaschegg and further in view of Kenley -- each of these rejections is also respectfully deemed to be obviated. The combined disclosures of the cited references would not have rendered obvious Applicants' presently claimed invention because the disclosures of the additional references do not rectify any of the above-described deficiencies of Twardowski and Polaschegg.

In view of the foregoing, this application is now in condition for allowance. If the examiner believes that an

interview might expedite prosecution, the examiner is invited to contact the undersigned.

Respectfully submitted,

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